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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,866	09/19/2006	Henry William Lupton	LRM-36143-A-US	8975
56/80 7590 08/05/2010 WHYTE HIRSCHBOECK DUDEK S.C. INTELLECTUAL PROPERTY DEPARTMENT 33 East Main Street, Suite 300 Madison, WI 53703-4655				
EXAMINER SMITH, FANGEMONIQUE A				
ART UNIT		PAPER NUMBER		
3736				
NOTIFICATION DATE		DELIVERY MODE		
08/05/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptomailbox@whdlaw.com
ekenrick@whdlaw.com

Office Action Summary

Application No.

10/590,866

Applicant(s)

LUPTON ET AL.

Examiner

Fangemonique Smith

Art Unit

3736

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 87-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 87-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on May 27, 2010. Examiner acknowledges the amendment of claims 87, 90-97 and 99-107. Claims 87-107 are pending.

Claim Rejections - 35 USC § 102

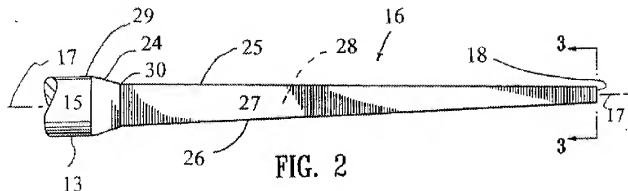
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

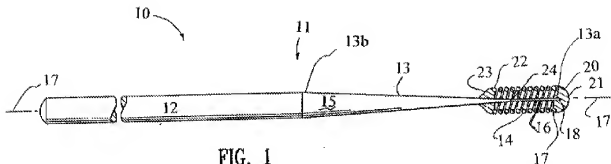
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 87-95, and 100-104 are rejected under 35 U.S.C. 102(e) as being anticipated by Jafari et al. (U.S. Patent Application Publication Number 2003/0013993).

In regard to claims 87-95 and 100-104, Jafari et al. disclose a guide wire having an elongate core member which extends between a proximal end and a distal end, and defines a longitudinally extending main central axis. The guide wire has a distal end which terminates in a terminal member extending axially from the guide wire. The terminal member of the Jafari et al. device tapers to a distal, elongated leading edge portion (Figure 2).



As shown above, the leading edge portion extends in a direction at an angle in the range of 1° to 90° relative to an axial direction defined by the main central axis. The Jafari et al. device further includes a first planar surface portion of the terminal member which converges towards an opposite second planar surface portion thereof towards the leading edge portion. The terminal member of the device includes a rectangular distal cross section with a circular proximal cross section. Jafari et al. disclose the first and second surface portions may also be concave (paragraph [0033]). Jafari et al. have first and second surface portions of the terminal member which are joined by spaced apart opposite third and fourth planar surface portions. The third and fourth surface portions of the terminal member are parallel to each other in an axial direction defined by the main central axis. Additionally, the maximum outer transverse cross-sectional area of the terminal member of the Jafari et al. device is substantially similar to the outer transverse cross-sectional area of the guide wire adjacent the terminal member (Figure 2). Jafari et al. disclose a helical coiled sleeve which extends along the core wire from the terminal member and terminates at a location intermediate the distal end and the proximal end of the core wire (Figure 1).



The terminal member of the Jafari et al. device is secured to the sleeve by brazing or soldering (paragraphs [0005]; [0025]). Jafari et al. further disclose the sleeve or engaging bore may be made of a radiopaque material.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 96-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jafari et al. (U.S. Patent Application Publication Number 2003/0013993) in view of Shabaz et al. (U.S. Patent Application Publication Number 2005/0065453).

In regard to claims 96-99, Jafari et al. disclose the features of the Applicant's invention as described above. Jafari et al. do not specifically disclose having curved third and fourth surfaces as part of the device. Shabaz et al. disclose a biopsy device which separates and collects tissue from a target site within a patient. The device disclosed by Shabaz et al. includes a probe

component having a penetrating distal tip with a first, second and third curved surface. Shabaz et al. disclose the penetrating distal tip also having a distal concave portion of a fourth surface portion of the tip. The leading edge portion of the tip disclosed by Shabaz et al. is radiused having a concave orientation from the first surface portion of the tip to the second surface portion of the tip. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a guide wire having an elongate core member which extends between a proximal end and a distal end, similar to that disclosed by Jafari et al., to include a third and fourth concave surface as a part of the tip design, similar to that disclosed by Shabaz et al., to allow penetration of the tip through occluding objects while gaining access to desired area.

6. Claims 105 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jafari et al. (U.S. Patent Application Publication Number 2003/0013993) in view of Hastings et al. (U.S. Patent Application Publication Number 2002/0019644).

In regard to claims 105 and 106, disclose the features of the Applicant's invention as described above. Jafari et al. do not specifically disclose the use of a magnetic material for guiding the device through to a desired target area. Hastings et al. disclose a guide wire device having a magnetic element located at the distal tip of the device to orient the tip as desired. The magnetic material is designed to facilitate directing the terminal member through a vascular system by way of a magnetic urging means located externally from the patient. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a guide wire having an elongate core member which extends between a proximal end and a distal end, similar to that disclosed by Jafari et al., to include a magnetic material located at the distal

tip of the device, similar to that disclosed by Hastings et al., to provide a mechanism which allows the user to orient the distal tip of the device in effort to access a desired target area.

7. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jafari et al. (U.S. Patent Application Publication Number 2003/0013993) in view of Wagner (U.S. Patent Number 5,135,483).

In regard to claim 107, Jafari et al. disclose the features of the Applicant's invention as described above. Jafari et al. do not specifically disclose using the guide wire in a re-canalising procedure. Wagner discloses a device and method for re-canalising a vascular occlusion in a human or animal subject. The device disclosed by Wagner includes method steps comprising urging a terminal member of a guide wire through an occlusion within the body of a patient. Wagner discloses using this procedure to remove occlusions from the lumen of the vessel. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a guide wire having an elongate core member which extends between a proximal end and a distal end, similar to that disclosed by Jafari et al., to include method steps of use which employs the device to remove occlusions from a body vessel, similar to that disclosed by Wagner, to clear arteries and veins of occluding material.

Response to Arguments

8. Applicant argues the Jafari et al. prior art reference does not disclose a structure disposed at the terminal end of a guidewire. Instead, Applicant indicates the Jafari reference has an intermediate smoothly tapered section. Examiner submits the tapered section is disposed at a terminal end of the guidewire. Applicant does not provide additional information regarding the

dimension of the terminal end. Examiner submits the tapered end of the Jafari et al. reference has been interpreted by the Examiner as the terminal end of the device and meets the claims as presented by Applicant. Applicant's arguments filed May 27, 2010 have been fully considered but they are not persuasive. The rejection stands.

9. Applicant argues the prior art is not a re-canalising guidewire as described by Applicant. Applicant's arguments filed May 27, 2010 have been fully considered but they are not persuasive. Examiner submits Jafari et al. indicate it would be desirable to make a guide wire better suit the purpose of use, including changing the diameter or dimensions of the device, which is determined by the application of the guide wire. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the dimensions of the device to be sized for different medical procedures such as re-canalising because one of ordinary skill in the art would expect the guide wire of Jafari et al. and the applicant's invention to perform equally well with either the dimensions taught by Jafari et al. or a modified dimension to be suited for re-canalising. Examiner further submits both dimensions would perform the same function of allowing the guide wire to be manipulated within an internal structure for opening an occlusion. Such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Jafari et al.

10. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., non-rigid piercing structure) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In*

re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, there are guide wires with both flexible tips as well as rigid tips. Changing the guidewire tip to be rigid versus flexible is a taught as a design modification in the art (U.S. Patent Number 6,340,441).

11. Applicant argues the Hastings et al. prior art reference is not a guidewire. In response to Applicant's amendments with respect to the Hastings et al. reference, Examiner submits that the structure of the Hastings et al. device is fully capable of performing the same type of navigating toward a desired location as the guidewire of the claimed invention. Also, the tip taught by Hastings et al. is fully capable of being used to modify the tip of the Jafari et al. reference to provide a magnetic tip similar to that disclosed by Applicant. Applicant's arguments with respect to the claims have been considered but are not persuasive. The rejection stands.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is (571)272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736